I. Introduction - System Overview

I. Introduction - System Overview

The system must be operated by knowledgeable users. It is essential that you have read and understood this manual before operating the system.

The **BELMONT FLUID MANAGEMENT SYSTEM**, FMS2000 infuses blood, replacement IV fluids or irrigation fluids warmed to physiologic temperature at user-set rates from 10 to 750 milliliters per minute (ml/min). Low infusion rates of 2.5 and 5.0ml/min (150 and 300ml/hr) are also available to keep the venous line open. No heating is provided at these low infusion rates.

The system monitors temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid infused, temperature, line pressure, alarm and status messages and proper procedures to proceed safely after an alarm situation. Keys appropriate to a particular point in the operation are displayed on the touch screen.

A battery backup allows for mobile transport of the patient and system. During battery operation, fluid warming is disabled while pump operation and safety monitoring remain active.

INDICATIONS FOR USE

- Infusion of crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
- Infusion of warmed fluid to re-warm patients after surgery or for hypothermia.
- Infusion of warmed fluid for irrigation in urology procedures.

CONTRAINDICATIONS

- The system should not be used where the desired flow rate is below 2.5 ml/min or above 750 ml/min.
- The system should not be used to warm platelets, cryo-precipitates, or granulocyte suspensions.
- This system is not intended for drug administration.
- Belmont *FMS2000* should not be used where rapid infusion is medically contraindicated.

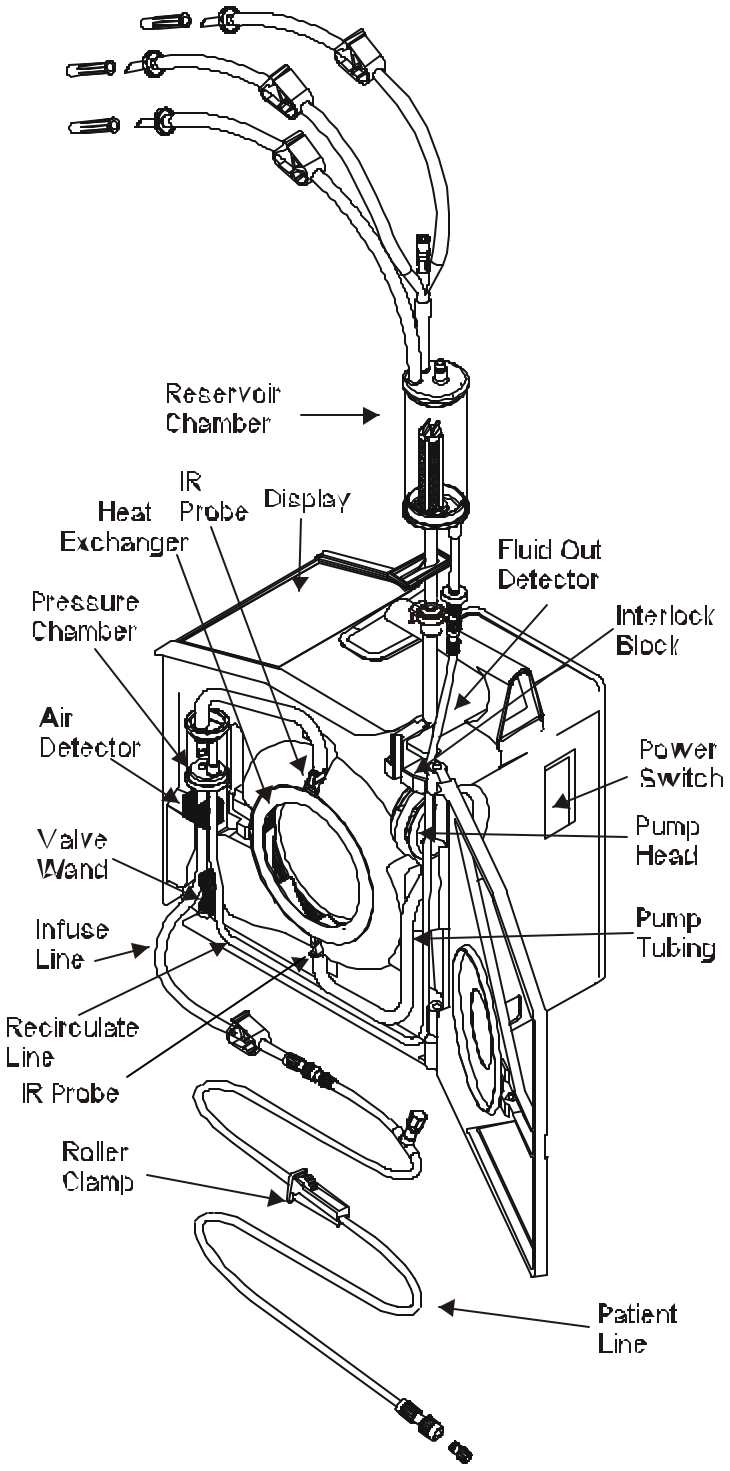
OVERVIEW OF THE BELMONT *FMS2000*

The complete system consists of the *FMS2000* **Control System**, which is mounted on an IV pole, and the *FMS2000* **System Disposable Set**.

The **Control System** consists of three major components:

- A high speed fluid pump.
- An efficient fluid warmer.
- A Monitoring/Alarm system for sensing and analyzing:
  - Infusate Flow Rate
  - Fluid Temperature
  - Line Pressure
  - Air Bubbles in the Infusate

The **Disposable Set** is preconnected and has a sterile fluid path. **It is intended for single patient use only**. It connects directly to fluid or blood bags and contains components necessary to pump and warm the infusate, and interfaces directly to temperature, air, and pressure sensors in the Control System. **The** *FMS2000* **can be used only with the supplied disposables.**



System Diagram Showing Main Components

FLUID PUMP

The roller type peristaltic fluid pump is designed to obtain low hemolysis, consume low power, to be light weight and very reliable. The pump head can be removed for cleaning. The pump is mounted near the top of the Control System just below the “Fluid Out" (Out of Fluid) Detector. The pump tubing is built into the disposable set.

HEATING SYSTEM AND TEMPERATURE MONITORING

Blood or replacement fluid is warmed as it passes through the heat exchanger. The heat exchanger consists of a plastic housing holding stainless steel rings used to transfer the heat to the fluid. Infrared temperature sensors which are mounted at the entrance and the exit of the heat exchanger, monitor the temperature of fluid as it enters and exits the heat exchanger. The temperature of the heated fluid as it leaves the heat exchanger is displayed on the screen. The system corrects for overheating or underheating and will shut off and alarm at unsafe conditions. The system is capable of heating fluids from 10°C to 37.5°C at 750 ml/min.

PRESSURE MONITORING

A pressure sensor monitors the line pressure of the infusate. Line pressure is directly influenced by the infusion set used. Larger bore catheters or needles result in lower line pressure allowing for higher flow rates. A guide for matching infusion set to flow rate and fluid viscosity is given in Chapter II.

If the sensor detects pressure which exceeds the limit set by the user, the pump automatically slows down to maintain the line pressure below the pressure limit. The system automatically resets the pressure limit to 300 mmHg, at power-up. If the line pressure suddenly increases, pumping and heating stop. An alarm sounds and "High Pressure" is displayed on the screen. High pressure in the line during infusion can not be transmitted back to the infusate bag. This high pressure sensing prevents fluid lines from "blowing out" if blocked.

AIR DETECTORS

Air in the system is vented through a hydrophobic filter at the top of the Reservoir Chamber in the Disposable. During infusion, after every 500 ml infused, the system will automatically recirculate any air in main fluid circuit back into the Reservoir Chamber to be vented. In addition, there are two (2) air detectors to monitor for air.

Fluid Out (Out of Fluid) Air Detector: This air detector is located closest to the fluid bag just above the fluid pump. If air is detected, pumping and heating stop. The alarm sounds and the "Fluid Out" warning message is displayed on the screen. A graphic message appears showing the location of the air detector involved, and gives instructions on how to clear the alarm and proceed safely.

In-line Air Detector: This air detector is located above the valve wand. If air is detected, the diversion valve is closed immediately to prevent air from reaching the patient line. Pumping and heating stop. An alarm sounds and the "Air detection" warning message is displayed on the screen. A graphic message appears showing the location of the air detector which signaled the warning and gives instructions on how to clear the alarm and proceed safely, using a special bypass operating mode.

ALARM AND ALARM MESSAGES

An alarm message is displayed on the screen whenever an error condition occurs which may require user intervention. At each alarm condition, the pump is stopped, the heater turned off, and the diversion valve closes, blocking fluid infusion to the patient, and rerouting fluid back to the reservoir.

See Chapter III: Alarm Messages and Troubleshooting Procedures for complete list of alarms.

CONTROL PANEL: DISPLAY AND KEYS

The control panel consists of the touch screen display, which incorporates a bright graphical display with touch pad keys. The display shows status and alarm messages at the top and middle, and contains the touch keys at the bottom.

CONTROL PANEL SUMMARY

Status Display:

- **Flow Rate in ml/min**
- **Volume Infused**
- **Infusate Temperature in °C**
- **Pressure in the Fluid Line in mm Hg**
- **Bolus Volume (when infusion of a fixed bolus of fluid is desired).**

Function Keys: The keys that control all system functions are displayed on the screen. The screen is changed each time a function key is pressed. Only keys that are relevant to the desired function are presented. The active key is highlighted.
There are three (3) different levels of sensitivity: Fast, Medium, and Slow. The key sensitivity is set at the factory to medium, but can be adjusted by the operator in SERVICE MODE.

See Chapter IV for 'Key Rate' sensitivity setup.

Alarm Display: Graphical alarm messages indicating where errors have occurred and suggested operator action.